1985-1986 ANNUAL SURVEY REPORT

U.S. PHARMACEUTICAL INDUSTRY

Pharmaceutical Manufacturers Association

ANNUAL SURVEY REPORT

PMA 1985-1986

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Foreword

The Pharmaceutical Manufacturers Association (PMA) is a nonprofit trade association of over 100 research-based pharmaceutical companies. These firms produce most of the ethical pharmaceuticals sold in the United States and a substantial portion of the world supply.

The Annual Survey is designed to provide information on the ethical pharmaceutical industry to business executives, financial analysts, educators, and other interested groups.

Survey questions are updated periodically and the scope of the survey expanded or reduced to reflect changing priorities. However, an effort is made to maintain continuity and comparisons with earlier surveys can be made in most categories.

Responses to surveys are reasonably uniform and consistent, but there are minor variations, from year to year. To compensate for these, adjustments are made based on supplementary data available to PMA from other sources. No adjustment has been made for inflation; data are presented in current dollars for manufacturers' sales and R&D expenditures.

Although this is a membership survey, selected operational totals include estimates for nonmember firms based on data obtained from other sources. For example, aggregate human-dosage form drug sales have been extrapolated to represent the entire industry. However, extrapolation was not possible for bulk sales, veterinary use pharmaceuticals, foreign data or R&D. In order to maintain continuity of the data, some firms who are no longer PMA member firms are represented by estimate in the data for PMA members.

TRENDS

1984-1986[a] Pharmaceutical Industry Operations

PMA Member Firms

Sales and R&D expenditures are expected to reach new record levels in 1986. Global sales are almost three times higher than sales ten years ago; global R&D expenditures have quadrupled. The trends for 1984-1986 are shown below.

- Global Sales, Ethical Pharmaceuticals, Human and Veterinary Use:
  1984 $29.9 billion, up 8.7% from 1983
  1985 $32.0 billion, up 7.0% from 1984
  1986 $36.1 billion, up 12.8% from 1985

- U.S. Sales[b], Human-Use, Dosage-Form Pharmaceuticals:
  1984 $19.3 billion, up 11.6% from 1983
  1985 $22.1 billion, up 14.5% from 1984
  1986 $24.8 billion, up 12.2% from 1985

- Global R&D Expenditures for Human and Veterinary-Use Pharmaceuticals:
  1984 $3.6 billion, up 12.5% from 1983
  1985 $4.1 billion, up 13.9% from 1984
  1986 $4.6 billion, up 12.2% from 1985

Table 1

[a]Figures for 1986 are budgeted or estimated figures.
[b]U.S. sales figures apply to all U.S. firms, not PMA member firms only.

U.S. Pharmaceutical Industry Sales & R&D Expenditures, 1961-1986[a] (millions of dollars) 1

Year	U.S. Sales[b]	Global Sales and R&D-PMA Member Firms		
		Sales Human and Veterinary[c]		R&D[d]
	Human Dosage	*Dosage Only*	*Dosage & Bulk*	*Human & Veterinary*
1986[e]	24,774	34,567	36,064	4,647
1985	22,065	30,698	32,026	4,078
1984	19,345	28,615	29,854	3,579
1983	17,278	26,254	27,506	3,218
1982	15,394	24,466	25,654	2,774
1981	13,000	22,378	23,530	2,340
1980	11,799	21,460	22,513	1,977[f]
1979	10,044	17,789	18,939	1,627
1978	9,156	15,463	16,431	1,404
1977	8,233	13,377	14,155	1,276
1976	7,669	12,295	13,035	1,164
1975	6,895	11,129	11,769	1,062
1974	6,085	9,755	10,361	942
1973	5,507	8,403	8,859	825
1972	5,018	7,576	7,950	726
1971	4,667	6,787	7,605	684
1970	4,322	6,226	6,657	619
1969	4,008	5,632	6,008	550
1968	3,655	5,097	5,482	495
1967	3,226	4,546	4,941	461
1966	3,011	4,105	4,509	416
1965	2,779	3,758	4,136	365
1964	2,479	3,331	3,643	310
1963	2,317	3,082	3,399	292
1962	2,199	2,866	3,170	259
1961	1,954	2,626	2,933	245

[a]Additional data are available to 1954. See earlier Annual Survey Reports.

[b]U.S. Sales of finished prescription and "otc ethical" dosage forms.

[c]Global sales are defined to include total ethical pharmaceutical sales within the United States, exports to nonaffiliated firms and sales abroad of U.S. affiliates. Figures apply to PMA member companies only. Historical series has been adjusted accordingly.

[d]Global R&D includes all ethical pharmaceutical research and development financed or conducted by U.S. pharmaceutical companies in the U.S. and abroad, and in the U.S. only by U.S. based subsidiaries of foreign-owned firms.

[e]PMA estimates based on member company budgeted figures or estimates.

[f]R&D figures for 1979 and 1980 reflect a 21% increase in expenditures; however, part of this increase is due to improved reporting of expenditures in foreign countries. Adjusting for this improved reporting results in an 18% increase.

SALES[a]

Highlights

U.S. sales continued the trend of double-digit percentage increases through 1984, but U.S. sales growth in 1985 slowed to 9%. Foreign sales increased by 4% in 1985, the largest increase since 1980. Sales of prescription legend products continue to represent more than 88% of the ethical market in the U.S. While European countries receive over 40% of sales abroad, the Pacific and Far East nations represent over 20% of sales in 1985. The leading selling product class in the U.S. is central nervous system products; anti-infectives are the leading sellers abroad. In the U.S. market, more than two-thirds of manufacturers' sales are now distributed through wholesalers.

1984 and 1985 Sales in the United States and Abroad

- U.S. sales volume rose 14% in 1984 and 9% in 1985; foreign sales volume increased by only 4% in 1984 and 4% in 1985.
- U.S. sales accounted for 66% of volume for U.S. manufacturers in 1985.
- Human-use dosage forms constitute 93% of all sales, U.S. and foreign.
- Exports amounted to $1,557 million in 1985, up 16% from 1983.

Tables 2 and 3.

Ethical Pharmaceuticals Sales Growth, (millions of dollars) 2

Year	Domestic Sales	Percent Change	Foreign Sales	Percent Change	Total	Percent Change
1983	$17,095.0		$10,411.2		$27,506.2	
1984	$19,403.1	+13.5%	$10,450.9	+.4%	$29,854.0	+8.5%
1985	$21,153.5	+9.0%	$10,872.3	+4.0%	$32,025.8	+7.3%

[a]Sales for PMA member firms only.

Ethical Pharmaceutical Sales[a] of PMA Member Firms, Domestic and Foreign: Shares of End-Use Totals, 1985 (millions of dollars)

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	Domestic U.S. Sales			Foreign Sales				Sales for Export Intra-Firm Tran-Actions[c]
	To Private Sector	To Govern-ments	Total Domestic Sales	Exports to Other Firms	Sales Abroad[b]	Total Foreign Sales	Total	
Dosage Form Human Use	$18,815.6 (63.3%)	$1,264.0 (4.3%)	$20,079.6 (67.6%)	$464.1 (1.5%)	$9,176.4 (30.9%)	$9,640.5 (32.4%)	$29,720.1 (100.0%)	$542.4
Dosage Form Veterinary Use	568.9 (58.2%)	.8 (.1%)	569.7 (58.3%)	48.5 (5.0%)	359.5 (36.7%)	408.0 (41.7%)	977.7 (100.0%)	50.0
Bulk Human Use	185.3 (27.5%)	.1 (d)	185.4 (27.5%)	144.9 (21.5%)	344.2 (51.0%)	489.1 (72.5%)	674.5 (100.0%)	232.1
Bulk Veterinary Use	318.8 (48.8%)		318.8 (48.8%)	41.9 (6.4%)	292.8 (44.8%)	334.7 (51.2%)	653.5 (100.0%)	33.0
TOTAL	$19,888.6 (62.1%)	$1,264.9 (3.9%)	$21,153.5 (66.0%)	$699.4 (2.2%)	$10,172.9 (31.8%)	$10,872.3 (34.0%)	$32,025.8 (100.0%)	$857.5

[a]Sales are before deducting cash discounts and other marketing expenses, but after returns and allowances (domestic returns and allowances totalled $585 million).

[b]Export sales are f.o.b. U.S. port. Domestic sales figures are f.o.b. plant or warehouse. In addition, transportation costs for domestic sales were $163 million and net value of discounts on domestic sales $411 million.

[c]Sales for Export Intra-Firm Transactions are sales to own International Division or for export to subsidiary abroad and are included as part of cost in Sales Abroad. Addition of the two export columns will provide aggregate ethical pharmaceutical exports.

[d]Less than .1 percent.

1985 Sales by Dosage Form

- Prescription drugs accounted for 89% of U.S. sales in the human use, dosage form category; over-the-counter ethical products accounted for 8% and the remainder came from sales of biologicals, diagnostics and other products.
- Government purchases of ethical pharmaceuticals constituted 6% of the total; 86% of these purchases were prescription drugs.

Domestic Sales of Dosage-Form, Human-Use Ethical Pharmaceuticals, 1985 (millions of dollars) 4

Dosage Form Human Use	To Private Sector	To Government	Total Domestic Sales
Prescription Legend[a]	$18,351.6	$1,198.4	$19,550.0 (88.6%)
Over-the-Counter Ethical[b]	1,595.0	59.9	1,654.9 (7.5%)
Biologicals[c]	434.9	94.7	529.6 (2.4%)
Diagnostic Products[d]	115.9	16.5	132.4 (.6%)
Other	180.1	18.5	198.6 (.9%)
Total, Dosage Form, Human Use	$20,677.5	$1,388.0	$22,065.5 (100.0%)

[a]Prescription Legend—A product which by federal law is available only by prescription from a licensed physician.

[b]Over-the-Counter Ethical—A drug product sold over the counter but primarily promoted to the professions. This does not include proprietary drugs (i.e., OTC products on display for purchase by customers).

[c]Biologicals—Bacterial and virus vaccine, antigens, antitoxins, toxoids, and analagous products (such as allergenic extracts) serums, plasmas, and other blood derivatives for human use.

[d]Dosage form, diagnostic agents for in-vivo use.

1985 Sales by Geographic Area

- Europe accounted for 42% of foreign sales; Latin America 17%; Japan, Australia and New Zealand 16%.
- The decline in the relative importance of the European and Latin American markets, first noted in 1980, continued in 1985. The share of total foreign sales in three areas increased—Japan, Australia, and New Zealand; Far East Pacific; and Canada.

Distribution of Foreign Sales* by Geographic Area, 1983 and 1985 — 5

Area	Percentage of Total Foreign Sales	
	1983	1985
Canada	7.7%	9.0%
Latin America (Central America, South America, excluding Cuba)	17.7%	17.3%
Western Europe (excluding Turkey, Yugoslavia and Albania; including Greece and Scandinavia)	43.5%	42.3%
Middle East	4.6%	3.6%
Africa	4.6%	4.4%
Far East Pacific (from Pakistan to Pacific Islands)	6.3%	6.9%
Japan, Australia, New Zealand	15.1%	15.7%
Socialist Bloc (Eastern Europe, USSR, Yugoslavia Albania, Cuba, Peoples' Republic of China, N. Korea, Laos, Cambodia and Vietnam)	.5%	.8%
Total	100.0%	100.0%

*Sales made abroad and exports to third parties.

1983 and 1985 Sales by Class of Customer

- Sales to wholesalers continued to increase, but sales to retailers as a percent of the total were down.
- Total hospital sales declined to 13.4%.
- From 1975 to 1985 the wholesalers' percentage share of sales increased by more than 40 percent.

Tables 6 and 7

Manufacturers Sales of Human-Use, Dosage-Form Products, in the United States, 1983, 1985 (millions of dollars) 6

Class of Customer	Sales 1983	Market Share 1983	Sales 1985	Market Share 1985
Wholesalers	$10,660.6	61.7%	$14,850.0	67.3%
Retailers	2,971.8	17.2	3,530.5	16.0
Private Hospitals	2,177.0	12.6	1,941.8	8.8
State and Local Government Hospitals	604.7	3.5	551.6	2.5
Federal Hospitals	432.0	2.5	463.4	2.1
Other Federal Government	207.3	1.2	353.0	1.6
Practitioners	121.0	.7	154.5	.7
Manufacturers, Repackagers and Other Direct Sales	103.7	.6	220.7	1.0
TOTAL	$17,278.1	100.0%	$22,065.5	100.0%

Ethical Pharmaceutical Manufacturers' Direct Human-Use Dosage-Form Sales in the United States by Class of Customer, 1975-1985 (odd years, percentage share of sales) 7

Class of Customer	1975	1977	1979	1981	1983	1985
Wholesalers	46.9%	49.1%	53.0%	59.2%	61.7%	67.3%
Retailers	27.6	25.5	22.5	18.0	17.2	16.0
Private Hospitals	14.7	15.1	14.9	13.9	12.6	8.8
State and Local Government Hospitals	4.6	4.5	4.0	3.9	3.5	2.5
Federal Hospitals	2.6	2.7	2.3	2.6	2.5	2.1
Other Federal Government	1.1	1.3	1.4	.9	1.2	1.6
Practitioners	1.2	1.1	1.2	.9	.7	.7
Manufacturers, Repackagers, and Other Direct Sales	1.3	.7	.7	.6	.6	1.0
TOTAL	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Domestic Sales by Product Class, Dosage-Form Ethical Drugs for Human Use, 1985 (millions of dollars)

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Product Class	Prescription Drugs Sales	Prescription Drugs Market Share	Over-the-Counter Ethicals Sales	Over-the-Counter Ethicals Market Share	Total Sales	Total Market Share
Central Nervous System	$ 5,219.8	26.7%	$ 382.4	23.1%	$ 5,602.2	26.4%
Anti-Infectives	3,440.8	17.6	140.7	8.5	3,581.5	16.9
Gastrointestinal & Genitourinary	1,740.0	8.9	354.1	21.4	2,094.1	9.9
Neoplasms and Endocrine	2,600.1	13.3	43.0	2.6	2,643.1	12.5
Vitamins and Nutrients	645.1	3.3	248.2	15.0	893.3	4.2
Cardiovasculars	4,164.2	21.3	0	0	4,164.2	19.6
Respiratory System	958.0	4.9	259.8	15.7	1,217.8	5.7
Dermatologicals	312.8	1.6	190.3	11.5	503.1	2.4
Other	469.2	2.4	36.4	2.2	505.6	2.4
TOTAL	$19,550.0	100.0%	$ 1,654.9	100.0%	$21,204.9	100.0%

1985 Sales by Product Class

- Products acting on the central nervous system continued to represent the largest product sales category, accounting for 26% of domestic dosage form sales in 1985.
- Other product classes, in order of sales rank in 1985, were cardiovasculars (20%), anti-infectives (17%), neoplasms and endocrine (13%), and gastrointestinal and genitourinary (10%).
- In foreign sales, anti-infectives are first, followed by drugs for the central nervous system and neoplasms and endocrine system. These three groups accounted for over half of the sales abroad.

Tables 8 and 9

Foreign Sales by Product Class, Dosage-Form Ethical Drugs for Human Use, 1985 (millions of dollars) 9

Product Class	1985	Percent
Anti-Infectives	$2,313.0	24.0%
Central Nervous System	1,533.7	15.9
Respiratory System	849.5	8.8
Gastrointestinal and Genitourinary	869.4	9.0
Neoplasms and Endocrine	1,350.3	14.0
Cardiovasculars	1,087.1	11.3
Vitamins and Nutrients	557.2	5.8
Dermatologicals	345.3	3.6
Biologicals	235.5	2.4
Diagnostic Agents	117.5	1.2
Other Pharmaceutical Preparations	382.0	4.0
TOTAL	$9,640.5	100.0%

Industry Employment

- PMA member companies employed an estimated 312,700 persons worldwide in pharmaceutical operations in 1985.
- 47% were employed abroad.
- 36% of all U.S. employees were in production, 27% in marketing, 22% in medical R&D, and the rest in administration, distribution, and other.

Domestic & Foreign Employment, Ethical Pharmaceuticals, in 1982-1985 — 10

	1982	1983	1984	1985
U.S. Employment	157,400	158,600	157,000	164,400
Production Workers	66,900	62,500	N/A*	58,600
Marketing	38,200	40,400	N/A	44,600
Medical Research and Development	28,100	31,800	N/A	35,800
Administrative	17,800	17,300	N/A	18,100
Distribution & Others	6,400	6,600	N/A	7,300
Foreign Employment	151,400	148,000	148,700	148,300
TOTAL	308,800	306,600	305,700	312,700

*Not available

R&D

Highlights

PMA members' continuing commitment to R&D is estimated at over $4.6 billion in 1986 and more than 80% of this spending is in the U.S. Manufacturers are now devoting the largest percentage of R&D funds, both here and abroad, to research on cardiovascular products. R&D expenditures in the U.S. now represent over 15% of total U.S. sales.

1983-1986 Research and Development

- Total R&D expenditures in 1985 reached $4.1 billion, up 14% from 1984. Expenditures for 1986 were budgeted at $4.6 billion.
- 96% of company R&D funds were spent on human-use pharmaceuticals and 4% on animal-use products.
- Government contracts increased from $6.0 million in 1984 to $8.0 million in 1985. $8.2 million was budgeted for 1986.

Table 11

R&D Expenditures for Ethical Pharmaceuticals: 1983, 1984, 1985 (actual) and 1986 (budgeted) PMA Member Firms (millions of dollars)

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	1983 Actual	1984 Actual	1985 Actual	1986 Budgeted
Company-Financed R&D Expenditures for Human-Use Pharms.:				
Amount spent in United States	$2,537.5	$2,842.7	$3,234.0	$3,661.8
Within Firm	2,151.3	2,380.5	2,693.7	3,017.9
Outside Firm	386.2	462.2	540.3	643.9
Amount spent in foreign countries	$ 525.4	$ 576.1	$ 677.1	$ 798.0
Within Firm	439.4	480.7	564.7	647.8
Outside Firm	86.0	95.4	112.4	150.2
TOTAL Human-Use R&D	$3,062.9	$3,418.8	$3,911.1	$4,459.8
Company-Financed R&D Expenditures for Veterinary-Use Pharms.:				
Amount spent in United States	$ 125.6	$ 133.7	$ 136.7	$ 151.5
Within Firm	113.9	121.8	124.6	140.0
Outside Firm	11.7	11.9	12.1	11.5
Amount spent in foreign countries	$ 20.9	$ 20.3	$ 21.8	$ 27.1
Within Firm	18.5	14.3	15.4	18.6
Outside Firm	2.4	6.0	6.4	8.5
TOTAL Veterinary R&D	$ 146.5	$ 154.0	$ 158.5	$ 178.6
TOTAL Company-Financed R&D for Pharmaceuticals	$3,209.4	$3,572.8	$4,069.6	$4,638.4
U.S. Government Grants and Contracts for Company-Conducted Pharmaceutical R&D	8.2	6.0	8.0	8.2
TOTAL Expenditures for Pharmaceutical R&D	$3,217.6	$3,578.8	$4,077.6	$4,646.6

1983-1985 Research and Development Expenditures Abroad

- The share of total R&D spending performed abroad was 17% in both 1984 and 1985. 18.0% was budgeted for 1986.

Tables 12 and 13

R&D Expenditures for Ethical Pharmaceuticals (millions of dollars) 1984 (actual), 1985 (actual), 1986 (budgeted)

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	1984		1985		1986	
	Amount	Change 1983-84	Amount	Change 1984-85	Amount	Change 1985-86
Company-Financed, for Human-Use Pharmaceuticals:						
Amount spent in U.S.	$2,842.7	+12.0%	$3,234.0	+13.8%	$3,661.8	+13.2%
Amount spent in foreign countries	576.1	+9.7%	677.1	+17.5%	798.0	+17.9%
Company-Financed, for Veterinary-Use Pharmaceuticals:						
Amount spent in U.S.	$ 153.7	+6.5%	$ 136.7	+2.2%	$ 151.5	+10.8%
Amount spent in foreign countries	20.3	−2.9%	21.8	+7.4%	27.1	+24.3%

Domestic and Foreign Shares of Company-Funded R&D Expenditures 1980-86 (percentages)

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	1980	1981	1982	1983	1984	1985	1986*
R&D Expenditures, Human-and-Animal-Use Pharmaceuticals							
Domestic	78.3	79.9	81.8	83.0	83.0	83.0	82.0
Foreign	21.7	20.1	18.2	17.0	17.0	17.0	18.0
TOTAL	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

*1986 figures are budgeted or estimated.

1983-1985 Research and Development Distribution of Expenditures

- The share of expenditures devoted to human-use drug research continued to increase slightly. Human-use drug research accounted for 95.2% of total expenditures in 1985 and 96.0% in 1986 (budgeted).
- The share of expenditures for intramural research in the United States for human-use drugs, about two-thirds of the total, remained relatively stable through 1985. Budgeted figures for 1986 show a small decline in this share.

Table 14

R&D Expenditures for Ethical Pharmaceuticals, Allocation of Funds (percentages) 1983, 1984, 1985 (actual) and 1986 (budgeted)

Category of R&D Expenditures for Ethical Pharmaceuticals	1983	1984	1985	1986 (budgeted)
Company-Financed R&D Expenditures for Human-Use Products:				
Percentage spent in the United States	78.86%	79.43%	79.31%	78.81%
Within firm	66.86	66.52	66.06	64.95
Outside firm	12.00	12.91	13.25	13.86
Percentage spent in foreign countries	16.33%	16.10%	16.61%	17.17%
Within firm	13.66	13.43	13.85	13.94
Outside firm	2.67	2.67	2.76	3.23
TOTAL Human-use R&D	95.19%	95.53%	95.92%	95.98%
Company-Financed R&D Expenditures for Veterinary-Use Products:				
Percentage spent in the United States	3.90%	3.73%	3.35%	3.26%
Within firm	3.54	3.40	3.05	3.01
Outside firm	.36	.33	.30	.25
Percentage spent in foreign countries	.65%	.57%	.54%	.58%
Within firm	.57	.40	.38	.40
Outside firm	.08	.17	.16	.18
TOTAL Veterinary R&D	4.55%	4.30%	3.89%	3.84%
TOTAL Company-Financed R&D	99.74	99.83	99.81	99.82
U.S. Government Grants and Contracts for Company-Conducted R&D	.26	.17	.19	.18
TOTAL Expenditures for R&D	100.00%	100.00%	100.00%	100.00%

Research by Geographic Area, 1983, 1985

- Over two-thirds, 67%, of the research funds spent abroad were spent in Western Europe in 1985. In 1983 the figure was 72%.
- Japan, Australia and New Zealand accounted for 19% of foreign expenditures, Canada for 7% and Latin America for 3%.

Distribution of R&D Expenditures Abroad by Geographic Area, 1983, 1985 — 15

Area	Percentage of Total 1983	1985
Canada	7.0%	7.3%
Latin America (Central America, South America, Caribbean, excluding Cuba)	4.1	3.0
Western Europe (excluding Turkey, Yugoslavia and Albania; including Greece and Scandinavia)	71.8	67.3
Middle East	.5	1.2
Africa	1.6	1.0
Far East and Pacific (from Pakistan to Pacific Islands)	1.1	.8
Japan, Australia and New Zealand	14.1	19.4
Socialist Bloc (including Eastern Europe, U.S.S.R., Yugoslavia, Albania, People's Republic of China, Laos, Cambodia and Vietnam)	0*	0*
TOTAL	100.0%	100.0%

*less than .1%

Research and Development Allocation of Expenditures to New Product Research

- 84% of R&D funds are spent for research and development of new products; 16% goes for improvement of existing products.
- Abroad, the ratio of new product/existing product expenditures is 73/27.

Tables 16 and 17

Company-Financed R&D Expenditures in the United States, 1985 (percentages) 16

	Human-and Veterinary-Use R&D 1985
Research for the Advancement of Scientific Knowledge and Development of New Products and Related Services	83.7%
Research Oriented to Significant Improvements and/or Modification of Existing Products	16.3%
TOTAL	100.0%

Company-Financed R&D Expenditures in Foreign Countries, 1985 (percentages) 17

	Human-and Veterinary-Use R&D 1985
Research for the Advancement of Scientific Knowledge and Development of New Products and Related Services	72.5%
Research Oriented to Significant Improvements and/or Modification of Existing Products	27.5%
TOTAL	100.0%

1983, 1985 Research and Development Allocation of Expenditures by Product Class

- More than 70% of the research funds went to investigations related to infections, central nervous system, neoplasms, and the heart.
- Cardiovascular product research led with 26% of the total in 1985.
- Increases in the relative share of total expenditures went to research on cardiovasculars, neoplasms and endocrine, gastrointestinal and respiratory products.
- Research expenditures abroad are most often directed to cardiovascular products. Research on anti-infectives, neoplasms, central nervous system, and gastrointestinal and genitourinary system also receive large shares of total expenditures.

Tables 18 and 19

U.S. R&D Expenditures for Pharmaceuticals, by Product Class, 1983, 1985 (percentages) 18

Product Class	1983	1985
Anti-infectives	16.8%	14.9%
Central Nervous System and Sense Organs	12.8	12.9
Cardiovasculars	22.7	25.8
Neoplasms, Endocrine System and Metabolic Diseases	16.3	18.1
Gastrointestinal and Genitourinary System	6.0	5.8
Respiratory	5.1	5.7
Biologicals	2.1	2.6
Dermatologicals	2.2	1.7
Vitamins	1.3	1.1
Diagnostic (in vivo)	.8	.7
Other	9.2	6.6
Veterinary Preparations	4.2	3.7
Veterinary Biologicals	.5	.4
TOTAL	100.0%	100.0%

R&D Expenditures Abroad for Pharmaceuticals, by Product Class, 1983, 1985 (percentages)

19

Product Class	1983	1985
Anti-infectives	17.2%	18.1%
Cardiovasculars	19.3	21.5
Central Nervous System and Sense Organs	12.2	14.9
Gastrointestinal and Genitourinary System	10.5	8.0
Neoplasms, Endocrine System and Metabolic Diseases	14.4	14.5
Respiratory	3.5	6.2
Dermatologicals	1.2	.9
Biologicals	1.5	2.6
Vitamins	3.4	1.7
Diagnostic (in vivo)	.9	.6
Other	12.1	7.6
Veterinary Preparations	3.8	3.4
Veterinary Biologicals	0.0	0.0
TOTAL	100.0%	100.0%

Research and Development
Allocation of Expenditures by Function

- About half of all R&D expenditures is allocated to Biological Screening and Pharmacological Testing, Clinical Evaluation, and Synthesis and Extraction.
- The largest share, 21%, is spent on Clinical Evaluation: Phases I, II, and III.

Distribution of U.S. R&D Expenditures for Ethical Pharmaceuticals by Function

20

Function	Percentage of Total 1983	1985
Clinical Evaluation: Phases I, II, III	20.0%	21.0%
Biological Screening and Pharmacological Testing	17.6	16.6
Synthesis and Extraction	10.9	11.6
Pharmaceutical Dosage Formulation and Stability Testing	9.9	9.3
Toxicology and Safety Testing	9.0	8.9
Process Development for Manufacturing and Quality Control	9.5	9.4
Clinical Evaluation: Phase IV	4.0	5.0
Regulatory, IND and NDA Preparation, Submission and Processing	4.4	4.4
Bioavailability Studies	2.5	2.9
Other	12.2	10.9
TOTAL	100.0%	100.0%

1982-1985 Research and Development Employment

- R&D employment, in PMA member firms totalled 44,700 in 1985, 80% of this total in the U.S. This total represents a 5% increase over 1984, and a 21% increase over 1982.
- The average R&D expenditure per R&D employee was $94,154 in 1985, 12% higher than the figure for 1983.
- Firms investing over $50 million in R&D employed about 83% of total R&D personnel. These firms also invested about 25% more per employee than firms spending $50 million or less.

Tables 21, 22, 23 and 24

R&D Personnel in the United States, by Position Level

21

Category	1982	1983	1985
Scientific and Professional	16,700	19,000	21,850
Technical	6,000	5,990	6,160
Supporting Staff	6,400	6,810	7,790
TOTAL	29,100	31,800	35,800

R&D Personnel in U.S. and Abroad, 1982-1985

22

Year	Grand Total	U.S.	Abroad
1982	37,000	29,100	7,900
	(100%)	(79%)	(21%)
1983	40,200	31,800	8,400
	(100%)	(79%)	(21%)
1984	42,600	34,100	8,500
	(100%)	(80%)	(20%)
1985	44,700	35,800	8,900
	(100%)	(80%)	(20%)

U.S. Intramural R&D Expenditures for Human- and Veterinary-Use Pharmaceuticals per R&D Employee, 1985 23

Annual R&D Expenditure	Average Expenditure per R&D Employee, 1985
Over $50 million	$97,847
$10-$50 million	80,069
Under $10 million	59,377
Average, All Firms	$94,154

R&D Employment by Company R&D Expenditures, 1985 24

Annual R&D Expenditures	Total	Scientific & Professional	Technicians	Supporting	Scientists per 100 R&D Employees
Over $50 million	29,800	18,280	5,120	6,400	61
$10-50 million	5,200	3,100	920	1,180	60
Under $10 million	800	470	120	210	59
Total	35,800	21,850	6,160	7,790	61

1985 Research and Development/Sales Ratio

- The percentage of the domestic pharmaceutical sales dollar allocated to domestic R&D increased to 14.8% in 1985. For 1986 the estimated percentage is 15.0%.

R&D as a Percentage of Sales, Ethical Pharmaceuticals 25

Year	1980	1981	1982	1983	1984	1985	1986*	Average 1980-1986
Ratio	11.7	13.1	13.8	14.4	14.4	14.8	15.0	13.9

Human and veterinary ethical pharmaceuticals. R&D is domestic U.S. only as financed by companies for internal and external performance. Sales basis: Domestic sales plus exports to other firms and intrafirm exports but excluding sales of foreign plants owned by U.S. firms. Data represent all PMA member firms.

*Estimated or Budgeted

Glossary

Definitions used in the 1985-1986 Survey

Biologicals—bacterial and virus vaccine, antigens, antitoxins, toxoids, and analogous products (such as allergenic extracts), serums, plasmas, and other blood derivatives for human use.

Bulk—For use as a pharmaceutical or medicinal product in further manufacture or in packaging by another company, or for processing in animal feeds (but not as nutritional ingredients), or in prescription compounding, etc.

Company or Firm—Manufacturers including parent, affiliated and subsidiary companies, without duplication engaged in production of ethical pharmaceuticals, biologicals, and diagnostic products.

Diagnostic Agents (in vivo)—Diagnostic products used in living body.

Employment—All full-time production workers as well as officers of the company, including employees engaged in the following activities: factory supervision above the working foreman level, sales, advertising, financial, clerical, executive, purchasing, legal, personnel, professional and technical.

1. *Production Workers*—Employees up through the working foreman level engaged in fabricating, processing, assembling, receiving, inspection, quality control, handling, packing, warehousing and storage, shipping, maintenance, repair, janitorial, watchman service, production development, record keeping, and other services associated with the production operations.
2. *Medical Research and Development*—Personnel engaged in research, research administration, clinical evaluation and development; excludes personnel in promotion, sales, market research, business administration, production and quality control.
3. *Sales and Marketing Research Employees*—Personnel in sales, advertising, sales promotion, market research, etc.
4. *Administrative Employees*—Personnel responsible for general management, accounting, finance, planning, personnel, purchasing office services, legal, secretarial, etc.
5. *Distribution*—Personnel responsible for distribution, including transportation and warehousing.

Employment Abroad—Total number of full-time employees, whether U.S. Citizens or not, of PMA member firms or any wholly owned overseas corporations, or corporations in which PMA member firms had a substantial or controlling interest.

Ethical Pharmaceuticals—Products, including biologicals and medicinal chemicals, used for the cure, alleviation, mitigation, treatment, prevention or diagnosis of disease in humans or animals and promoted primarily to the medical, pharmacy and allied professions; includes products for over-the-counter ethical sales as well as for ultimate dispensing by prescription only.

Exports—*"f.o.b."* U.S. port.

a) To other firms: sales to third parties only.

b) Intrafirm transactions: sales and shipments at billed (not end sales) value to subsidiaries and affiliates for further handling, processing or packaging.

Government Grants and Contracts for Company-Conducted R&D—Grants and contractual payments received by companies from governmental agencies for pharmaceutical research and development.

Over-the-Counter Ethical—A drug product sold over the counter but primarily promoted to the professions. This does not include proprietary drugs (i.e., OTC products on display for purchase by consumers).

Prescription Legend—A drug product which by Federal law is available only by prescription from a licensed physician.

Research and Development—The term includes basic and applied research as well as development activities carried on or supported in the pharmaceutical, biological, chemical, medical and related sciences, including psychology and psychiatry, if the purpose of such activities is concerned ultimately with the utilization of scientific principles in understanding diseases or in improving health.

R&D Expenditures—The total cost incurred for all pharmaceutical research and development activity, including cost of salaries, other direct costs, service, routine supplies, and supporting costs, plus a fair share of overhead (administration, depreciation, space charges, rent, etc.).

Cost of drugs or medical research and development conducted on grant or contract for other companies are excluded. Conversely, total outlays for all research and development work contracted to others (manufacturers, independent research laboratories, academic institutions, etc.) are included.

Research and Development Expenditures Within Firm—Includes research and development expenditures in the United States and foreign countries in a firm's own research laboratories.

Research and Development Expenditures Outside Firm—Research and development funds contracted or granted to such organizations as commercial laboratories, private practitioners, consultants, etc., educational institutions, non-profit research institutions, manufacturing and other companies or other research performing organizations.

R&D Manpower—Personnel engaged in research, research administration, clinical evaluation and development; excludes personnel in promotion, sales, market research, business administration, production and quality control.

Research and Development Scientific and Professional Staff—Includes all persons whose work requires the application for research and development of knowledge, skills and scientific techniques, in the life, physical, engineering, or mathematical sciences, acquired through the completion of a four-year college course (or its equivalent) with a major in these fields or in medicine or other health professions. Excludes persons who have formal training in the sciences but who are not actively engaged in research and development.

Research and Development Supporting Staff—Includes persons who provide literature, clinical, statistical, or other services specifically for R&D staff and technicians.

Research and Development Technicians—Includes persons actually engaged in technical work at a level which requires knowledge of the life, physical engineering, or mathematical sciences comparable at least to that acquired through technical institutes, junior colleges, or other formal post-high school training less extensive than four-year college training, or through equivalent on-the-job training or experience. However, also included are persons who hold an academic degree at the bachelor's level or above.

Sales—Sales figures are reported as billed (before deducting cash discounts on sales and other marketing expenses), less returns and allowances. Includes sales value of products bought and resold without further processing or repacking as well as the dollar value of products made from own materials for other manufacturer's resale. Excluded are all royalty payments, interest and other income.

Sales Abroad—Actual sales consummated in foreign countries other than "Sales for Exports to Other Firms." Such sales by affiliates and subsidiaries or other operations abroad are reported in dollars, computed at December 31 rate of exchange (when possible) for the year shown. Where a partially owned subsidiary is involved, the firm's share is determined on a proportionate profit-sharing basis.

Sales for Export—Reported as "f.o.b. U.S. port."

1. *To Other Firms*—Excludes intracompany transactions, includes sales to third parties only.
2. *Intracompany Transactions*—Includes sales and shipments to subsidiaries or affiliates for further handling, processing, or finishing by them. Reported as net billed value, not end sales values.

Sales by Product Class—Estimated distribution of domestic sales of ethical pharmaceutical and biological dosage-form preparations in accordance with the classification system used in the annual Current Industrial Reports from the Bureau of the Census.

Sales to Governments—Sales or shipments made directly to federal, state or local government agencies, hospitals and clinics.

Sales to Private Sector—Sales through regular marketing channels for end-use other than by government agency administration or distribution.

Pharmaceutical Manufacturers Association
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ANNUAL SURVEY REPORT

PMA 1986-1987

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Foreword

The Pharmaceutical Manufacturers Association (PMA) is a non-profit trade association of over 100 research-based pharmaceutical companies. These firms produce most of the ethical pharmaceuticals sold in the United States and a substantial portion of the world supply.

The Annual Survey is designed to provide information on the ethical pharmaceutical industry to business executives, financial analysts, educators, and other interested groups.

Survey questions are updated periodically and the scope of the survey expanded or reduced to reflect changing priorities. However, an effort is made to maintain continuity and comparisons with earlier surveys can be made in most categories.

Responses to surveys are reasonably uniform and consistent, but there are minor variations, from year to year. To compensate for these, adjustments are made based on supplementary data available to PMA from other sources. No adjustment has been made for inflation; data are presented in current dollars for manufacturers' sales and R&D expenditures.

Although this is a membership survey, selected operational totals include estimates for nonmember firms based on data obtained from other sources. For example, aggregate human-dosage form drug sales have been extrapolated to represent the entire industry. However, extrapolation was not possible for bulk sales, veterinary use pharmaceuticals, foreign data or R&D. In order to maintain continuity of the data, some firms who are no longer PMA member firms are represented by estimate in the data for PMA members.

TRENDS

1985-1987[a] Pharmaceutical Industry Operations PMA Member Firms

Global sales in 1987 were estimated to exceed $41 billion, nearly three times higher than sales ten years ago. Global R&D expenditures exceeded $5 billion for the first time and have more than quadrupled since 1977. The trends for 1985-1987 are shown below.

- Global Sales, Ethical Pharmaceuticals, Human and Veterinary Use:
  1985 $32.0 billion, up 7.0% from 1984
  1986 $37.1 billion, up 15.9% from 1985
  1987 $41.2 billion, up 11.1% from 1986

- U.S. Sales[b], Human-Use, Dosage-Form Pharmaceuticals:
  1985 $22.1 billion, up 14.5% from 1984
  1986 $25.2 billion, up 14.0% from 1985
  1987 $28.3 billion, up 12.3% from 1986

- Global R&D Expenditures for Human and Veterinary Use Pharmaceuticals:
  1985 $4.1 billion, up 13.9% from 1984
  1986 $4.7 billion, up 14.6% from 1985
  1987 $5.4 billion, up 14.9% from 1986

Table 1

[a]Figures for 1987 are budgeted or estimated figures.
[b]U.S. sales figures apply to all U.S. firms, not PMA member firms only.

U.S. Pharmaceutical Industry Sales & R&D Expenditures, 1961-1987[a] (millions of dollars) 1

Year	U.S. Sales[b]	Global Sales and R&D-PMA Member Firms		
		Sales		R&D[d]
		Human and Veterinary[c]		
	Human Dosage	*Dosage Only*	*Dosage & Bulk*	*Human & Veterinary*
1987[e]	28,252	39,632	41,246	5,376
1986	25,227	35,685	37,137	4,740
1985	22,065	30,698	32,026	4,078
1984	19,345	28,615	29,854	3,579
1983	17,278	26,254	27,506	3,218
1982	15,394	24,466	25,654	2,774
1981	13,000	22,378	23,530	2,340
1980	11,799	21,460	22,513	1,977[f]
1979	10,044	17,789	18,939	1,627
1978	9,156	15,463	16,431	1,404
1977	8,233	13,377	14,155	1,276
1976	7,669	12,295	13,035	1,164
1975	6,895	11,129	11,769	1,062
1974	6,083	9,755	10,361	942
1973	5,507	8,403	8,839	825
1972	5,018	7,576	7,930	726
1971	4,667	6,787	7,605	684
1970	4,322	6,226	6,637	619
1969	4,008	5,632	6,008	550
1968	3,655	5,097	5,482	495
1967	3,226	4,546	4,941	461
1966	3,011	4,105	4,509	416
1965	2,779	3,758	4,136	365
1964	2,479	3,331	3,643	310
1963	2,317	3,082	3,399	292
1962	2,199	2,866	3,170	259
1961	1,954	2,626	2,933	245

[a]Additional data are available to 1954. See earlier Annual Survey Reports.

[b]U.S. Sales of finished prescription and "otc ethical" dosage forms.

[c]Global sales are defined to include total ethical pharmaceutical sales within the United States, exports to nonaffiliated firms and sales abroad of U.S. affiliates. Figures apply to PMA member companies only. Historical series has been adjusted accordingly.

[d]Global R&D includes all ethical pharmaceutical research and development financed or conducted by U.S. pharamaceutical companies in the U.S. and abroad, and in the U.S. only by U.S. based subsidiaries of foreign-owned firms.

[e]PMA estimates based on member company budgeted figures or estimates.

[f]R&D figures for 1979 and 1980 reflect a 21% increase in expenditures; however, part of this increase is due to improved reporting of expenditures in foreign countries. Adjusting for this improved reporting results in an 18% increase.

SALES[a]

Highlights

U.S. sales increased 9% in 1985 and 14% in 1986. Foreign sales increased by 20% in 1986, due in part to the sharp decline in the value of the dollar. Sales of prescription legend products represent almost 90% of the ethical market in the U.S. European countries receive over 45% of sales abroad; the Pacific and Far East nations represent about one fourth of sales in 1986. The leading selling product class in the U.S. is central nervous system products; anti-infectives are the leading sellers abroad. In the U.S. market, more than two-thirds of manufacturers' sales are distributed through wholesalers.

1985-1987 Sales in the United States and Abroad

- U.S. sales volume rose 9% in 1985, and 14% in 1986, and was projected to increase by 12% in 1987; foreign sales volume increased by 4% in 1985, 20% in 1986, and an estimated 9% in 1987.
- U.S. sales accounted for 65% of volume for U.S. manufacturers in 1986 and 1987.
- Exports amounted to $2,044 million in 1986, up 31% from 1985.

Tables 2 and 3

Ethical Pharmaceuticals Sales Growth, (millions of dollars) **2**

Year	Domestic Sales	Percent Change	Foreign Sales	Percent Change	Total	Percent Change
1984	$19,403.1	+13.5%	$10,450.9	+.4%	$29,854.0	+ 8.5%
1985	$21,153.5	+9.0%	$10,872.3	+4.0%	$32,025.8	+ 7.3%
1986	$24,106.8	+14.0%	$13,030.5	+19.9%	$37,137.3	+16.0%
1987	$27,016.0	+12.1%	$14,230.0	+9.2%	$41,246.0	+11.1%

[a]Sales for PMA member firms only.

Ethical Pharmaceutical Sales[a] of PMA Member Firms, Domestic and Foreign: Shares of End-Use Totals, 1986 (millions of dollars)

3

	Domestic U.S. Sales				Foreign Sales			Sales for Export Intra-Firm Trans-actions[c]
	To Private Sector	To Govern-ments	Total Domestic Sales	Exports to Other Firms	Sales Abroad[b]	Total Foreign Sales	Total	
Dosage Form	$21,530.1	$1426.1	$22,956.2	$543.8	$11,112.0	$11,655.8	$34,612.0	$770.5
Human Use	(62.2%)	(4.1%)	(66.3%)	(1.6%)	(32.1%)	(33.7%)	(100.0%)	
Dosage Form	631.6	.9	632.5	35.7	405.1	440.8	1073.3	49.4
Veterinary Use	(58.9%)	(.1%)	(59.0%)	(3.3%)	(37.7%)	(41.0%)	(100.0%)	
Bulk	213.8	3.6	217.4	136.6	425.8	562.4	779.8	415.4
Human Use	(27.4%)	(.5%)	(27.9%)	(17.5%)	(54.6%)	(72.1%)	(100.0%)	
Bulk	300.7		300.7	41.3	330.2	371.5	672.2	51.5
Veterinary Use	(44.7%)		(44.7%)	(6.2%)	(49.1%)	(55.3%)	(100.0%)	
TOTAL	$22,676.2	$1,430.6	$24.106.8	$757.4	$12,273.1	$13,030.5	$37,137.3	$1,286.8
	(61.1%)	(3.8%)	(64.9%)	(2.0%)	(33.1%)	(35.1%)	(100.0%)	

[a]Sales are before deducting cash discounts and other marketing expenses, but after returns and allowances (domestic returns and allowances totalled $663 million).

[b]Export sales are f.o.b. U.S. port. Domestic sales figures are f.o.b. plant or warehouse. In addition, transportation costs for domestic sales were $166 million and net value of discounts on domestic sales $448 million.

[c]Sales for Export Intra-Firm Transacitons are sales to own International Division or for export to subsidiary abroad and are included as part of cost in Sales Abroad. Addition of the two export columns will provide aggregate ethical pharmaceutical exports.

1986 Domestic Sales of Dosage Form Products

- Prescription drugs accounted for 89% of U.S. sales in the human use, dosage form category; over-the-counter ethical products accounted for 6% and the remainder came from sales of biologicals, diagnostics and other products.
- Government purchases of ethical pharmaceuticals constituted 6% of the total; 85% of these purchases were prescription drugs.

Domestic Sales of Dosage-Form, Human-Use Ethical Pharmaceuticals, 1986 (millions of dollars) 4

Dosage Form Human Use	To Private Sector	To Government	Total Domestic Sales
Prescription Legend[a]	$21,166.8	$1,326.5	$22,493.3 (89.2%)
Over-the-Counter Ethical[b]	1,480.4	58.6	1,539.0 (6.1%)
Biologicals[c]	642.5	133.7	776.2 (3.1%)
Diagnostic Products[d]	132.2	21.8	154.0 (.6%)
Other	237.6	26.5	264.1 (1.0%)
Total, Dosage Form, Human Use	$23,659.5	$1,567.1	$25,226.6 (100.0%)

[a]Prescription Legend—A drug product which by federal law is available only by prescription from a licensed physician.

[b]Over-the-Counter Ethical—A drug product sold over the counter but primarily promoted to the professions. This does not include proprietary drugs (i.e., OTC products on display for purchase by customers).

[c]Biologicals—Bacterial and virus vaccine, antigens, antitoxins, toxoids, and analagous products (such as allergenic extracts) serums, plasmas, and other blood derivatives for human use.

[d]Dosage form, diagnostic agents for in-vivo use.

1986 Sales by Geographic Area

- Europe accounted for 45% of foreign sales; Japan, Australia and New Zealand 19%; Latin America 12%.
- Three markets increased their shares of total foreign sales in 1986—Canada; Western Europe and Japan, Australia and New Zealand.

Distribution of Foreign Sales* by Geographic Area, 1985 and 1986 — 5

Area	Percentage of Total Foreign Sales	
	1985	1986
Canada	9.0%	11.1%
Latin America (Central America, South America, excluding Cuba)	17.3%	12.4%
Western Europe (excluding Turkey, Yugoslavia and Albania; including Greece and Scandinavia	42.3%	45.5%
Middle East	3.6%	2.3%
Africa	4.4%	3.4%
Far East Pacific (from Pakistan to Pacific Islands)	6.9%	5.3%
Japan, Australia, New Zealand	15.7%	19.3%
Socialist Bloc (Eastern Europe, USSR, Yugoslavia, Albania, Cuba, Peoples' Republic of China, N. Korea, Laos, Cambodia and Vietnam	.8%	.7%
Total	100.0%	100.0%

*Sales made abroad and exports to third parties.

1985 and 1986 Sales by Class of Customer

- Sales to wholesalers continued to increase, but sales to retailers as a percent of the total were down.
- Total hospital sales declined from 13.4% to 12.7%.
- From 1974 to 1986 the wholesalers' percentage share of sales increased by more than 50 percent.

Tables 6 and 7

Manufacturers Sales of Human-Use, Dosage-Form Products, in the United States, 1985, 1986 (millions of dollars) 6

Class of Customer	Sales 1985	Market Share 1985	Sales 1986	Market Share 1986
Wholesalers	$14,850.0	67.3%	$17,238.8	68.3%
Retailers	3,530.5	16.0	3,907.3	15.5
Private Hospitals	1,941.8	8.8	2,003.4	8.0
State and Local Government Hospitals	551.6	2.5	581.2	2.3
Federal Hospitals	463.4	2.1	603.6	2.4
Other Federal Government	353.0	1.6	382.3	1.5
Practitioners	154.5	.7	256.7	1.0
Manufacturers, Repackagers and Other Direct Sales	220.7	1.0	253.3	1.0
TOTAL	$22,065.5	100.0%	$25,226.6	100.0%

Ethical Pharmaceutical Manufacturers' Direct Human-Use Dosage-Form Sales in the United States by Class of Customer, 1974-1986 (even years, percentage share of sales)

7

Class of Customer	1974	1976	1978	1980	1982	1985*	1986
Wholesalers	45.2%	48.5%	51.4%	57.3%	59.6%	67.3%	68.3%
Retailers	28.1	26.4	22.8	20.8	18.0	16.0	15.5
Private Hospitals	15.6	14.8	16.0	12.7	13.7	8.8	8.0
State and Local Government Hospitals	4.8	4.5	4.2	4.1	3.8	2.5	2.3
Federal Hospitals	2.6	2.5	2.4	2.5	2.5	2.1	2.4
Other Federal Government	1.2	1.3	1.4	1.2	1.1	1.6	1.5
Practitioners	1.5	1.2	1.2	1.0	.8	.7	1.0
Manufacturers, Repackagers, and Other Direct Sales	1.0	.8	.6	.4	.5	1.0	1.0
TOTAL	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

*1984 figures are not available

1986 Sales by Product Class

- Products acting on the central nervous system continued to represent the largest product sales category, accounting for 25% of domestic dosage form sales in 1986.
- Other product classes, in order of U.S. sales rank in 1986, were cardiovasculars (20%), anti-infectives (17%), neoplasms and endocrine (13%), and gastrointestinal and genitourinary (11%).
- In foreign sales, anti-infectives are first, followed by cardiovasculars and central nervous system. These three groups accounted for over half of the sales abroad.

Tables 8 and 9

Foreign Sales by Product Class, Dosage-Form Ethical Drugs for Human-Use, 1986 (millions of dollars) 9

Product Class	1986	Percent
Anti-Infectives	$ 2,408.9	20.7%
Central Nervous System	1,804.1	15.5
Respiratory System	895.0	7.7
Gastrointestinal and Genitourinary	1,131.3	9.7
Neoplasms and Endocrine	1,439.6	12.4
Cardiovasculars	2,181.3	18.7
Vitamins and Nutrients	585.7	5.0
Dermatologicals	319.4	2.7
Biologicals	355.8	3.0
Diagnostic Agents	150.0	1.3
Other Pharmaceutical Preparations	384.7	3.3
TOTAL	$11,655.8	100.0%

Industry Employment

- PMA member companies employed an estimated 319,090 persons worldwide in pharmaceutical operations in 1986.
- 47% were employed abroad.
- 37% of all U.S. employees were in production, 27% in marketing, and 27% in medical R&D.

Domestic & Foreign Employment, Ethical Pharmaceuticals, in 1984-1986

10

	1984	1985	1986
U.S. Employment	157,000	164,400	170,590
Production Workers	N/A*	58,600	63,600
Marketing	N/A	44,600	46,300
Medical Research and Development	N/A	35,800	37,790
Administrative	N/A	18,100	16,800
Distribution & Others	N/A	7,300	6,100
Foreign Employment	148,700	148,300	148,500
TOTAL	305,700	312,700	319,090

*Not available

R&D

Highlights

PMA members' continuing commitment to R&D is estimated at over $5.4 billion in 1987 and more than 80% of this spending is in the U.S. Manufacturers are devoting the largest percentage of R&D funds, both here and abroad, to research on cardiovascular products. R&D expenditures in the U.S. represent over 15% of total U.S. sales.

1984-1987 Research and Development

- Total R&D expenditures in 1986 reached $4.7 billion, up 15% from 1985. Expenditures for 1987 were budgeted at $5.4 billion.
- 96% of company R&D funds were spent on human-use pharmaceuticals, and 4% on animal-use products.
- Government contracts decreased from $8.0 million in 1985 to $4.1 million in 1986. $4.6 million was budgeted for 1987.

Table 11

R&D Expenditures for Ethical Pharmaceuticals: 1984, 1985, 1986 (actual) and 1987 (budgeted) PMA Member Firms (millions of dollars)

11

	1984 Actual	1985 Actual	1986 Actual	1987 Budgeted
Company-Financed R&D Expenditures for Human Use Pharms.:				
Amount spent in United States	$2,842.7	$3,234.0	$3,720.9	$4,252.8
Within Firm	2,380.5	2,693.7	3,101.1	3,491.5
Outside Firm	462.2	540.3	619.8	761.3
Amount spent in foreign countries	$ 576.1	$ 677.1	$ 836.0	$ 920.7
Within Firm	480.7	564.7	700.7	760.8
Outside Firm	95.4	112.4	135.3	159.9
TOTAL Human-Use R&D	$3,418.8	$3,911.1	4,556.9	$5,173.5
Company-Financed R&D Expenditures for Veterinary Use Pharms.:				
Amount spent in United States	$ 133.7	$136.7	$ 150.0	$ 165.4
Within Firm	121.8	124.6	137.7	151.1
Outside Firm	11.9	12.1	12.3	14.3
Amount spent in foreign countries	$ 20.3	$ 21.8	$ 29.1	$ 32.9
Within Firm	14.3	15.4	21.0	23.7
Outside Firm	6.0	6.4	8.1	9.2
TOTAL Veterinary R&D	$ 154.0	$ 158.5	$ 179.1	$ 198.3
TOTAL Company-Financed R&D for Pharmaceuticals	$3,572.8	$4,069.6	$4,736.0	$5,371.8
U.S. Government Grants and Contracts for Company-Conducted Pharmaceutical R&D	6.0	8.0	4.1	4.6
TOTAL Expenditures for Pharmaceutical R&D	$3,578.8	4,077.6	$4,740.1	$5,376.4

1985-1987 Research and Development Expenditures Abroad

- R&D spending abroad by PMA members increased more than 20% in 1986, resulting in an increase in the foreign share of total R&D. The share of total R&D spending performed abroad was 17% in 1985 and 18.0% in 1986. 18.0% was budgeted for 1987.

Tables 12 and 13

R&D Expenditures for Ethical Pharmaceuticals (millions of dollars) 1985 (actual) 1986 (actual), 1987 (budgeted)

12

	1985		1986		1987	
	Amount	Change 1984-85	Amount	Change 1985-86	Amount	Change 1986-87
Company-Financed, for Human-Use Pharmaceuticals:						
Amount spent in U.S.	$3,234.0	+13.8%	$3,720.9	+15.1%	$4,252.8	+14.3%
Amount spent in foreign countries	677.1	+17.5%	836.0	+23.5%	920.7	10.1%
Company-Financed, for Veterinary-Use Pharmaceuticals:						
Amount spent in U.S.	136.7	+2.2%	$ 150.0	+9.7%	$ 165.4	+10.3%
Amount spent in foreign countries	21.8	+7.4%	29.1	+33.5%	32.9	+13.1%

Domestic and Foreign Shares of Company-Funded R&D Expenditures 1981-87 (percentages)

13

	1981	1982	1983	1984	1985	1986	1987*
R&D Expenditures, Human-and-Animal-Use Pharmaceuticals							
Domestic	79.9	81.8	83.0	83.0	83.0	82.0	82.0
Foreign	20.1	18.2	17.0	17.0	17.0	18.0	18.0
TOTAL	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

*1987 figures are budgeted or estimated.

1984-1987 Research and Development Distribution of Expenditures

- The share of expenditures devoted to human-use drug research continued to increase slightly. Human-use drug research accounted for 96.1% of total expenditures in 1986 and 96.2% in 1987 (budgeted).
- The share of expenditures for intramural research in the United States for human-use drugs, about two-thirds of the total, has shown a small decline each year since 1983. Budgeted figures for 1987 show a decline of about 5%.

Table 14

R&D Expenditures for Ethical Pharmaceuticals, Allocation of Funds (percentages) 1984, 1985, 1986 (actual) and 1987 (budgeted)

14

Category of R&D Expenditures for Ethical Pharmaceuticals	1984	1985	1986	1987 (budgeted)
Company-Financed R&D Expenditures for Human Use Products:				
Percentage spent in the United States	79.43%	79.31%	78.50%	79.10%
Within Firm	66.52	66.06	65.42	64.94
Outside Firm	12.91	13.25	13.08	14.16
Percentage spent in foreign countries	16.10%	16.61%	17.64%	17.12%
Within Firm	13.43	13.85	14.78	14.15
Outside Firm	2.67	2.76	2.86	2.97
TOTAL Human-Use R&D	95.53%	95.92%	96.14%	96.22%
Company-Financed R&D Expenditures for Veterinary Use Products:				
Percentage spent in United States	3.73%	3.35%	3.16%	3.08%
Within Firm	3.40	3.05	2.90	2.81
Outside Firm	.33	.30	.26	.27
Percentage spent in foreign countries	.57%	.54%	.61%	.61%
Within firm	.40	.38	.44	.44
Outside firm	.17	.16	.17	.17
TOTAL Veterinary R&D	4.30%	3.89%	3.77%	3.69%
TOTAL Company-Financed R&D	99.83	99.81	99.91	99.91
U.S. Government Grants and Contracts for Company-Conducted R&D	.17	.19	.09	.09
TOTAL Expenditures for R&D	100.0%	100.0%	100.0%	100.0%

Research by Geographic Area, 1985, 1986

- More than 71% of the research funds spent abroad were spent in Western Europe in 1986. In 1985 the figure was 67%.
- Japan, Australia and New Zealand accounted for 18% of foreign expenditures, Canada for 8% and Latin America for 2%.

Distribution of R&D Expenditures Abroad by Geographic Area, 1985, 1986 — 15

Area	Percentage of Total 1985	1986
Canada	7.3%	7.5%
Latin America (Central America, South America, Caribbean, excluding Cuba)	3.0	2.1
Western Europe (excluding Turkey, Yugoslavia and Albania; including Greece and Scandinavia)	67.3	71.1
Middle East	1.2	.4
Africa	1.0	.6
Far East and Pacific (from Pakistan to Pacific Islands)	.8	.6
Japan, Australia and New Zealand	19.4	17.6
Socialist Bloc (including Eastern Europe, U.S.S.R., Yugoslavia, Albania, People's Republic of China, Laos, Cambodia and Vietnam)	0*	.1
TOTAL	100.0%	100.0%

*less than .1%

Research and Development Allocation of Expenditures to New Product Research

- 84% of R&D funds are spent for research and development of new products; 16% goes for improvement of existing products.
- Abroad, the ratio of new product/existing product expenditures is 78/22.

Tables 16 and 17

Company-Financed R&D Expenditures in the United States, 1986 (percentages) 16

	Human-and Veterinary-Use R&D 1986
Research for the Advancement of Scientific Knowledge and Development of New Products and Related Services	83.5%
Research Oriented to Significant Improvements and/or Modification of Existing Products	16.5%
TOTAL	100.0%

Company-Financed R&D Expenditures in Foreign Countries, 1986 (percentages) 17

	Human-and Veterinary-Use R&D 1986
Research for the Advancement of Scientific Knowledge and Development of New Products and Related Services	77.7%
Research Oriented to Significant Improvement and/or Modification of Existing Products	22.3%
TOTAL	100.0%

1985, 1986 Research and Development Allocation of Expenditures by Product Class

- More than 70% of the research funds went to investigations related to infections, central nervous system, neoplasms, and the heart.
- Cardiovascular product research led with 26% of the total in 1986.
- Increases in the relative share of the toal expenditures went to research on central nervous system and respiratory products.
- Research expenditures abroad are most often directed to cardiovascular products. Research on anti-infectives, neoplasms, and central nervous system also receive large shares of total expenditures.

Tables 18 and 19

U.S. R&D Expenditures for Pharmaceuticals, by Product Class, 1985, 1986 (percentages) 18

Product Class	1985	1986
Anti-Infectives	14.9%	13.9%
Central Nervous System and Sense Organs	12.9	14.2
Cardiovasculars	25.8	25.8
Neoplasms, Endocrine System and Metabolic Diseases	18.1	18.1
Gastrointestinal and Genitourinary System	5.8	5.7
Respiratory	5.7	6.2
Biologicals	2.6	2.3
Dermatologicals	1.7	2.0
Vitamins	1.1	.5
Diagnostic (in vivo)	.7	.5
Other	6.6	7.4
Veterinary Preparations	3.7	3.1
Veterinary Biologicals	.4	.3
TOTAL	100.0%	100.0%

R&D Expenditures for Pharmaceuticals, by Product Class, 1985, 1986 (percentages)

19

Product Class	1985	1986
Anti-Infectives	18.1%	14.6%
Cardiovasculars	21.5	25.6
Central Nervous System and Sense Organs	14.9	13.7
Gastrointestinal and Genitourinary System	8.0	8.2
Neoplasms, Endocrine System and Metabolic Diseases	14.5	11.0
Respiratory	6.2	7.5
Dermatologicals	.9	2.0
Biologicals	2.6	3.5
Vitamins	1.7	1.4
Diagnostic (in vivo)	.6	1.2
Other	7.6	7.9
Veterinary Preparations	3.4	3.4
Veterinary Biologicals	0.0	0.0
TOTAL	100.0%	100.0%

Research and Development Allocation of Expenditures by Function

- About half of all R&D expenditures is allocated to Biological Screening and Pharmacological Testing, Clinical Evaluation, and Synthesis and Extraction.
- The largest share, 23%, is spent on Clinical Evaluation: Phases I, II, and III.

Distribution of U.S. R&D Expenditures for Ethical Pharmaceuticals by Function 20

Function	Percentage of Total 1985	1986
Clinical Evaluation: Phases I, II, III	21.0%	22.7%
Biological Screening and Pharmacological Testing	16.6	15.5
Synthesis and Extraction	11.6	11.3
Pharmaceutical Dosage Formulation and Stability Testing	9.3	9.8
Toxicology and Safety Testing	8.9	8.6
Process Development for Manufacturing and Quality Control	9.4	9.5
Clinical Evaluation: Phase IV	5.0	3.7
Regulatory, IND and NDA Preparation, Submission and Processing	4.4	4.4
Bioavailability Studies	2.9	2.6
Other	10.9	11.9
TOTAL	100.0%	100.0%

1983-1986 Research and Development Employment

- R&D employment in PMA member firms totalled 47,770 in 1986, 80% of this total in the U.S. This total represents a 7% increase over 1985.
- The average R&D expenditure per R&D employee in the U.S. was $87,796 in 1986, 7% higher than the figure for 1985.
- Firms investing over $50 million in R&D employed about 87% of total R&D personnel in the U.S.

Tables 21, 22, 23 and 24

R&D Personnel in the United States, by Position Level

21

Category	1983	1985	1986
Scientific and Professional	19,000	21,850	24,500
Technical	5,990	6,160	6,250
Supporting Staff	6,810	7,790	7,520
TOTAL	31,800	35,800	38,270

R&D Personnel in U.S. and Abroad, 1982-1985

22

Year	Grand Total	U.S.	Abroad
1982	37,000	29,100	7,900
	(100%)	(79%)	(21%)
1983	40,200	31,800	8,400
	(100%)	(79%)	(21%)
1984	42,600	34,100	8,500
	(100%)	(80%)	(20%)
1985	44,700	35,800	8,900
	(100%)	(80%)	(20%)
1986	47,770	38,270	9,500
	(100%)	(80%)	(20%)

U.S. Intramural R&D Expenditures for Human and Veterinary-Use Pharmaceuticals per R&D Employee, 1985-1986

23

Annual R&D Expenditure	Average Expenditure per R&D Employee	
	1985*	1986
Over $50 million	$85,743	$90,237
$10-$50 million	70,688	80,480
Under $10 million	61,000	33,693
Average, All Firms	82,357	87,796

*Revised

R&D Employment by Company R&D Expenditures, 1986

24

Annual R&D Expenditures	Total	Scientific & Professional	Technicians	Supporting	Scientists per 100 R&D Employees
Over $50 million	33,240	21,660	5,220	6,360	65
$10-50 million	4,240	2,440	720	1,080	58
Under $10 million	790	400	310	80	51
Total	38,270	24,500	6,250	7,520	64

Research and Development/Sales Ratio

- The percentage of the domestic pharmaceutical sales dollar allocated to domestic R&D was 14.8% in 1986. For 1987 the estimated percentage is 15.1%.

R&D as a Percentage of Sales, Ethical Pharmaceuticals 25

Year	1981	1982	1983	1984	1985	1986	1987*	Average 1981-1987*
Ratio	13.1	13.8	14.4	14.4	14.8	14.8	15.1	14.3

Human and veterinary ethical pharmaceuticals. R&D is domestic U.S. only as financed by companies for internal and external performance. Sales basis: Domestic sales plus exports to other firms and intrafirm exports but excluding sales of foreign plants owned by U.S firms. Data represents all PMA member firms.

*Estimated or Budgeted

Glossary

Definitions used in the 1986-1987 Survey

Biologicals—bacterial and virus vaccine, antigens, antitoxins, toxoids, and analogous products (such as allergenic extracts), serums, plasmas, and other blood derivatives for human use.

Bulk—For use as a pharmaceutical or medicinal product in further manufacture or in packaging by another company, or for processing in animal feeds (but not as nutritional ingredients), or in prescription compounding, etc.

Company or Firm—Manufacturers including parent, affiliated and subsidiary companies, without duplication engaged in production of ethical pharmaceuticals, biologicals, and diagnostic products.

Diagnostic Agents (in vivo)—Diagnostic products used in living body.

Employment—All full-time production workers as well as officers of the company, including employees engaged in the following activities: factory supervision above the working foreman level, sales, advertising, financial, clerical, executive, purchasing, legal, personnel, professional and technical.

1. *Production Workers*—Employees up through the working foreman level engaged in fabricating, processing, assembling, receiving, inspection, quality, control, handling, packing, warehousing and storage, shipping, maintenance, repair, janitorial, watchman service, production development, record keeping, and other services associated with the production operations.
2. *Medical Research and Development*—Personnel engaged in research, research administration, clinical evaluation and development; excludes personnel in promotion, sales, market research, business administration, production and quality control.
3. *Sales and Marketing Research Employees*—Personnel in sales, advertising, sales promotion, market research, etc.
4. *Administrative Employees*—Personnel responsible for general management, accounting, finance, planning, personnel, purchasing office services, legal, secretarial, etc.
5. *Distribution*—Personnel responsible for distribution, including transportation and warehousing.

Employment Abroad—Total number of full-time employees, whether U.S. citizens or not, of PMA member firms or any wholly owned overseas corporation, or corporations in which PMA member firms had a substantial or controlling interest.

Ethical Pharmaceuticals—Products, including biological and medicinal chemicals, used for the cure, alleviation, mitigation, treatment, prevention or diagnosis of disease in humans or animals and promoted primarily to the medical, pharmacy and allied professions; includes products for over-the-counter ethical sales as well as for ultimate dispensing by prescription only.

Exports—"f.o.b.," U.S. port.

a) To other firms: sales to third parties only.

b) Intrafirm transactions: sales and shipments at billed (not end sales) value to subsidiaries and affiliates for further handling, processing or packaging.

Governmental Grants and Contracts for Company-Conducted R&D—Grants and contractual payments received by companies from governmental agencies for pharmaceutical research and development.

Over-The-Counter Ethical—A drug product sold over the counter but primarily promoted to the professions. This does not include proprietary drugs (i.e., OTC products on display for purchase by consumers).

Prescription Legend—A drug product which by Federal law is available only by prescription from a licensed physician.

Research and Development—The term includes basic and applied research as well as development activities carried on or supported in the pharmaceutical, biological, chemical, medical and related sciences, including psychology and psychiatry, if the purpose of such activities is concerned ultimately with the utilization of scientific principles in understanding diseases or in improving health.

R&D Expenditures—The total cost incurred for all pharmaceutical research and development activity, including cost of salaries, other direct costs, service, routine supplies, and supporting costs, plus a fair share of overhead (administration, depreciation, space charges, rent, etc.).

Costs of drugs or medical research and development conducted on grant or contract for other companies are excluded. Conversely, total outlays for all research and development work contracted to others (manufacturers, independent research laboratories, academic institutions, etc.) are included.

Research and Development Expenditures Within Firm—Includes research and development expenditures in the United States and foreign countries in the firm's own research laboratories.

Research and Development Expenditures Outside Firm—Research and development funds contracted or granted to such organizations as commercial laboratories, private practitioners, consultants, etc., educational institutions, non-profit research institutions, manufacturing and other companies or other research performing organizations.

R&D Manpower—Personnel engaged in research, research administration, clinical evaluation and development: excludes personnel in promotion, sales, market research, business administration, production and quality control.

Research and Development Scientific and Professional Staff—Includes all persons whose work requires the application for research and development of knowledge, skills and scientific techniques, in the life, physical, engineering, or mathematical sciences, acquired through the completion of a four-year college course (or its equivalent) with a major in these fields or in medicine or other health professions. Excludes persons who have formal training in the sciences but who are not actively engaged in research and development.

Research and Development Support Staff—Includes persons who provide literature, clinical, statistical, or other services specifically for R&D staff and technicians.

Research and Development Technicians—Includes persons actually engaged in technical work at a level which requires knowledge of the life, physical engineering, or mathematical sciences comparable at least to that acquired through technical institutes, junior colleges, or other formal post- high school training less extensive than four-year college training, or through equivalent on-the-job training or experience. However, also included are persons who hold an academic degree at the bachelor's level or above.

Sales—Sales figures are reported as billed (before deducting cash discounts on sales and other marketing expense), less returns and allowances. Includes sales value of products bought and resold without further processing or repacking as well as the dollar value of products made from own materials for other manufacturer's resale. Excluded are all royalty payments, interest and other income.

Sales Abroad—Actual sales consummated in foreign countries other than "Sales for Exports or Other Firms." Such sales by affiliates and subsidiaries or other operations abroad are reported in dollars, computed at December 31 rate of exchange (when possible) for the year shown. Where a partially owned subsidiary is involved, the firm's share is determined on a proportionate profit-sharing basis.

Sales for Export—Reported as "f.o.b. U.S. port."

1. *To Other Firms*—Excludes intracompany transactions, includes sales to third parties only.
2. *Intracompany Transactions*—Includes sales and shipments to subsidiaries or affiliates for further handling, processing, or finishing by them. Reported as net billed value, not end sales values.

Sales by Product Class—Estimated distribution of domestic sales of ethical pharmaceutical and biological dosage-form preparations in accordance with the classification system used in the annual Current Industrial Reports from the Bureau of the Census.

Sales to Governments—Sales or shipments made directly to federal, state or local government agencies, hospitals and clinics.

Sales to Private Sector—Sales through regular marketing channels for end-use other than by government agency administration or distribution.